REMARKS

This is a full and timely response to the outstanding Office Action mailed December 28, 2009. Reconsideration of the application and allowance of presently pending claims, are respectfully requested.

A. Present Status of Patent Application

Claims 20-31 remain pending in the present application.

Drawings

Applicant notes that the drawings filed Apr. 20, 2004 have been accepted.

B. Response to Action

1. Claims 22-23 and 31 have been objected to because of the dependency with withdrawn claim 21. The Examiner's assumption has been adopted, as the dependency of claim 22 has been changed from claim 21 to claim 20, which effectively corrects the dependency of claims 22-23 and 31. Accordingly, the Applicant respectfully requests withdrawal of the objection.

2. Claim Rejections under 35 U.S.C. § 103(a) over Heinonen (US 6,530,370) and further in view of Hamilton et al. (US 2002/0162553, hereinafter "Hamilton").

Claim 20 has been rejected under 35 U.S.C. § 103(a) over Heinonen and further in view of Hamilton. The analysis of obviousness was set forth in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In order to establish a *prima facie* case of obviousness, three basic criteria must be met:

> First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of the references. Second, there must be a *reasonable*

> *expectation of success*. Finally, the prior art reference or combined references must teach or suggest *all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art*, and not based on applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); (*emphasis added*).

The Applicant respectfully traverses the rejection as failing the *Graham* test.

Regarding independent claim 20, the rejection fails at least the first and third elements of the *Graham* test. Regarding the third element of the *Graham* test, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The Examiner has contended that Heinonen discloses and/or teaches a pressure-generating circuit that contains a first gas flow of sufficiently high-volume and a respiratory circuit that contains a second gas flow of lower volume than the first gas flow. (*See* claim 20). This limitation requires that the pressure generating circuit have a high gas flow, and the respiratory circuit have a lower gas flow. A complete review of Heinonen reveals that the first gas flow, as shown in Heinonen's Fig. 1, as tube 8, is provided by a ventilator 4. The Examiner contends that a second gas flow is provided by pump 36 into the respiratory circuit 18 by pressure line 38. However, pressure line 38 is connected to nebulizer apparatus 1, which provides a nebulized pharmaceutical agent. The reservoir 34 is pressurized by pump 36. At no point does Heinonen disclose, teach, or suggest that pump 36 provides any pressurized flow into respiratory circuit 18. "In operation, valve 40 is opened responsive to a signal from cable 42 and liquid flows through conduit 32 and transport line 32a due to the pressurizing gas in reservoir 34." (*See* Heinonen, col. 6, lines 39-41). As this passage from Heinonen shows, the flow from pump 36 is strictly used to force a liquid from reservoir 34 to the nebulizing apparatus 1. It does not introduce a second gas flow into the respiratory circuit, as required by claim 20. Therefore, the combination of art fails to disclose, teach, or

suggest *all the claim limitations*. Accordingly, the rejection violates the third element of the *Graham* test.

In addition, there is no description of, nor evidence that, the flow from pump 36 is less than the flow from ventilator 4. Since claim 20 requires that the second gas flow is of lower volume than the first gas flow, and Heinonen in view of Hamilton fail to disclose, teach, or suggest this limitation, the rejection fails to teach or suggest *all the claim limitations.* Accordingly, the rejection of claim 20 violates the third element of the *Graham* test.

The Examiner continues by alleging that Hamilton shows a continuous positive pressure, but Hamilton does not disclose a first gas flow of sufficiently high-volume and a second gas flow of lower volume than the first gas flow. (*See* claim 20). Hamilton, as admitted by the Examiner, is simply used to show a CPAP system, but this system does not function equivalently to the system claimed. Specifically, Hamilton does not disclose two gas flows of different volumes. Hamilton discloses the following:

> Low flow O_2 is also supplied to a nebulizer 26 from a nebulizer outlet 28 and a nebulizer shut off valve 30 (incorporated in the pressure regulator as will be described in more detail). The output of the nebulizer is combined with the O_2 delivered to the patient's mask through the tube 25 in a conventional manner. (Hamilton, [0040]).

As stated in Hamilton, the output of the nebulizer is combined with the O_2 delivered to the patient in a conventional manner. So, the nebulizer in Hamilton is not "a vibrating aperture nebulizer coupled to the respiratory circuit," as required by claim 20, since an O_2 flow is required to force the output from the nebulizer into O_2 flow delivered to the patient's mask, resembling a jet nebulizer. There is no discussion, description, or disclosure of providing a lower gas flow in the respiratory circuit than a gas flow in the pressure-generating circuit, nor of a vibrating aperture nebulizer, in Hamilton. Accordingly, the combination of art fails to disclose, teach, or suggest every limitation of claim 20, in violation of the third element of the *Graham* test.

In addition, claim 20 requires that the aerosolized medicament be introduced into the pressure-assisted breathing system at a location outside the high-volume flow of gas in the pressure-generating circuit. This structure avoids the dilution of the

aerosolized medicament by the high-volume gas flow in the pressure-generating circuit and results in an increased amount of aerosolized medicament delivered to the patient. This limitation is supported in the specification, e.g., in paragraphs [0020], [0022-0023].

As pointed out by the Examiner, Heinonen shows a pressure-generating circuit (8) and a respiratory circuit (18) adapted to be coupled to a patient interface device (col. 4, lines 52-64), wherein the pressure-generating circuit contains a first gas flow (from 8), but does not show a second gas flow of lower volume than the first gas flow. Hamilton shows a continuous positive pressure, but Hamilton does not disclose a first gas flow of sufficiently high-volume and a second gas flow of lower volume than the first gas flow, nor does Hamilton disclose a vibrating aperture nebulizer, as required by claim 20.

The Examiner contends that it would have been obvious to one skilled in the art to modify the ventilator system with the vibrating aperture nebulizer system taught by Heinonen with the CPAP respiratory therapy system taught by Hamilton. The Applicant disagrees.

Regarding the first element of the *Graham* test, Heinonen teaches away from a combination with Hamilton. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The Examiner is asked to note the following teachings of Heinonen:

> Disadvantages in the use of pneumatic nebulizers include the following. ... Because of the gas flow from the nebulizer, control over the inhalation gas composition is lost. Also, due to passage of the driving gas through the nozzle, impingement of the drug on the baffle, etc., pneumatic nebulizers are noisy. This may contribute to the discomfort of the subject. And, as controlling the commencing and stopping of a drug agent spray is difficult and is not very accurate, pneumatic nebulizers are commonly active during both inhalation and exhalation. This obviously decreases the efficiency of drug delivery as measured by the ratio of the amount of drug

> supplied to nebulizer and the amount of drug actually delivered into the subject's airways. (*See* Heinonen, col. 1, lines 46-64.)

The Examiner is asked to take note of the fact that Heinonen goes on to argue that the ultrasonic nebulizer allows for better control. Thus, it is clear that Heinonen teaches away from the use of a jet nebulizer (which is an element of Hamilton). *See* Hamilton [0045]. Therefore, Heinonen teaches away from the combination of features proposed by the Examiner, and the rejection of claim 20 must be withdrawn.

However, even assuming, *arguendo,* that it would have been obvious to combine the teachings of Heinonen and Hamilton as proposed by the Examiner, such combination does not result in the invention of claim 20 because the combination fails to include the step of introducing the aerosolized medicament into the CPAP system at a location outside the high-volume gas flow of the pressure-generating circuit of the CPAP system, thereby avoiding the dilution of the aerosolized medicament and increasing the amount of aerosolized medicament delivered to the patient's respiratory system, or providing a second gas flow in the respiratory circuit of lower volume than the first gas flow in the pressure-generating circuit. For either of these reasons, the rejection of claim 20 violates the third element of the *Graham* test, and must be withdrawn. Reconsideration and allowance of claim 20 is respectfully requested.

3. Claim Rejections under 35 U.S.C. § 103(a) over Heinonen in view of Hamilton, as applied to claim 20, and further in view of Power (US 2002/0002975).

Claims 22-23 and 30 have been rejected under 35 U.S.C. § 103(a) over Heinonen and further in view of Hamilton. The analysis of obviousness was set forth in *Graham*, *supra*.

Regarding the rejection of claim 22, the Examiner contends that Power discloses a reservoir having one unit dose of medicament. However, Power discloses simply that "Information regarding, for example, the type of medication contained within the medication cup 2 or suitable dosages, or periods in which to use the medication may be

provided on the sealing sheet 19. The information may be, for example, printed onto the sheet 19, or affixed with a label. The information may be, for example, in bar code format." (*See* Power, [0072]). The mere disclosure of the terms 'suitable dosages' does not obviate a claim directed to "a reservoir having a capacity equal to one unit dose of medicament" or that "substantially all of the contents of the reservoir [are] delivered to the patient's respiratory system," as required by claim 22.

First, Power fails to disclose or teach that the medication cup may contain one unit dose of a medicament. Instead, Power teaches that what may constitute a dose may be printed on a label, presumably for use in administering the proper amount of medicament to the medication cup. However, this source of human error is eliminated by the claimed invention in claim 22, since the reservoir in claim 22 fits exactly one unit dose of medicament, and no measuring is needed to determine the quantity to be administered to the reservoir.

In addition, Power fails to disclose or teach that the medication cup is completely depleted after treating a patient. Instead, the medication cup could have any amount of medicament added, and treatment may last for a variable length of time. This introduces another source of human error, in that the medicament could be administered for too short or too long of a time, thereby rendering the treatment less effective and/or dangerous.

For these reasons, the rejection of claim 22 violates the third element of the *Graham* test, as the addition of Power does not render claim 22 obvious after the application of Heinonen in view of Hamilton to claim 20. Accordingly, withdrawal of the rejection of claim 22 is respectfully requested.

Regarding the rejection of claim 23, this claim depends from claim 20 and therefore incorporate all the limitations of claim 20. Claim 20 is believed to be allowable over Heinonen in view of Hamilton. Since Power has been added to allegedly show additional limitations of claim 23, claim 23 is believed to be allowable over the combination of art due to its dependence. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claim 23 is respectfully requested.

Regarding the rejection of claim 30, Power fails to disclose an endotracheal tube that is used as a patient interface device, as required by claim 30. Accordingly, the rejection violates the third element of the *Graham* test, and must be withdrawn. In addition, claim 30 depends from claim 24, which, as argued later, is believed to be allowable. Therefore, claim 30 is also believed to be allowable. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claim 30 is respectfully requested.

4. Claim Rejections under 35 U.S.C. § 103(a) over Heinonen, Hamilton, and Power, in further view of Merrill (US 3,715,432).

Claims 24-30 have been rejected under 35 U.S.C. § 103(a) over Heinonen, Hamilton, and Power, in further view of Merrill. The analysis of obviousness was set forth in *Graham*, *supra*.

Independent claim 24, from which claims 25-30 depend, is rejected by the Examiner for the same reasons as claim 20 was rejected, except for the showing of a liquid surfactant being delivered to patient's respiratory system. The Applicant disagrees with the Examiner's position for the same reasons as stated above in regard to the rejection of claim 20. Specifically, the Applicant respectfully traverses the rejection as failing the *Graham* test.

The rejection fails at least the first and third elements of the *Graham* test. Regarding the third element of the *Graham* test, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The Examiner has contended that Heinonen discloses and/or teaches a pressure-generating circuit that contains a first gas flow of sufficiently high-volume and a respiratory circuit that contains a second gas flow of lower volume than the first gas flow. (*See* claim 24). This limitation requires that the pressure generating circuit have a

high gas flow, and the respiratory circuit have a lower gas flow. A complete review of Heinonen reveals that the first gas flow, as shown in Heinonen's Fig. 1, as tube 8, is provided by a ventilator 4. The Examiner contends that a second gas flow is provided by pump 36 into the respiratory circuit 18 by pressure line 38. However, pressure line 38 is connected to nebulizer apparatus 1, which provides a nebulized pharmaceutical agent. The reservoir 34 is pressurized by pump 36. At no point does Heinonen disclose, teach, or suggest that pump 36 provides any pressurized flow into respiratory circuit 18. "In operation, valve 40 is opened responsive to a signal from cable 42 and liquid flows through conduit 32 and transport line 32a due to the pressurizing gas in reservoir 34." (*See* Heinonen, col. 6, lines 39-41). As this passage from Heinonen shows, the flow from pump 36 is strictly used to force a liquid from reservoir 34 to the nebulizing apparatus 1. It does not introduce a second gas flow into the respiratory circuit, as required by claim 24. Therefore, the combination of art fails to disclose, teach, or suggest *all the claim limitations*. Accordingly, the rejection violates the third element of the *Graham* test.

In addition, there is no description of, nor evidence that, the flow from pump 36 is less than the flow from ventilator 4. Since claim 24 requires that the second gas flow is of lower volume than the first gas flow, and Heinonen, Hamilton, and Power, in view of Merrill fail to disclose, teach, or suggest this limitation, the rejection fails to teach or suggest *all the claim limitations*. Accordingly, the rejection of claim 24 violates the third element of the *Graham* test.

The Examiner continues by alleging that Hamilton shows a continuous positive pressure, but Hamilton does not disclose a first gas flow of sufficiently high-volume and a second gas flow of lower volume than the first gas flow. (*See* claim 24). Hamilton, as admitted by the Examiner, is simply used to show a CPAP system, but this system does not function equivalently to the system claimed. Specifically, Hamilton does not disclose two gas flows of different volumes. Hamilton discloses the following:

> Low flow O_2 is also supplied to a nebulizer 26 from a nebulizer outlet 28 and a nebulizer shut off valve 30 (incorporated in the pressure regulator as will be described in more detail). The output of the

> nebulizer is combined with the O_2 delivered to the patient's mask through the tube 25 in a conventional manner. (Hamilton, [0040]).

As stated in Hamilton, the output of the nebulizer is combined with the O_2 delivered to the patient in a conventional manner. So, the nebulizer in Hamilton is not "a vibrating aperture nebulizer coupled to the respiratory circuit," as required by claim 24, since an O_2 flow is required to force the output from the nebulizer into O_2 flow delivered to the patient's mask, resembling a jet nebulizer. There is no discussion, description, or disclosure of providing a lower gas flow in the respiratory circuit than a gas flow in the pressure-generating circuit, nor of a vibrating aperture nebulizer, in Hamilton. Accordingly, the combination of art fails to disclose, teach, or suggest every limitation of claim 24, in violation of the third element of the *Graham* test.

In addition, claim 24 requires that the aerosolized surfactant be introduced into the pressure-assisted breathing system at a location outside the high-volume flow of gas in the pressure-generating circuit. This structure avoids the dilution of the aerosolized surfactant by the high-volume gas flow in the pressure-generating circuit and results in an increased amount of aerosolized surfactant delivered to the patient. This limitation is supported in the specification, e.g., in paragraphs [0020], [0022-0023].

As pointed out by the Examiner, Heinonen shows a pressure-generating circuit (8) and a respiratory circuit (18) adapted to be coupled to a patient interface device (col. 4, lines 52-64), wherein the pressure-generating circuit contains a first gas flow (from 8), but does not show a second gas flow of lower volume than the first gas flow. Hamilton shows a continuous positive pressure, but Hamilton does not disclose a first gas flow of sufficiently high-volume and a second gas flow of lower volume than the first gas flow, nor does Hamilton disclose a vibrating aperture nebulizer, as required by claim 24.

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The Examiner is asked to take note of the fact that Heinonen goes on to argue that the ultrasonic nebulizer allows for better control. Thus, it is clear that Heinonen teaches away from the use of a jet nebulizer (which is an element of Hamilton). *See* Hamilton [0045]. Therefore, Heinonen teaches away from the combination of features proposed by the Examiner, and the rejection of claim 24 must be withdrawn.

However, even assuming, *arguendo*, that it would have been obvious to combine the teachings of Heinonen and Hamilton as proposed by the Examiner, such combination does not result in the invention of claim 24 because the combination fails to include the step of introducing the aerosolized surfactant into the CPAP system at a location outside the high-volume gas flow of the pressure-generating circuit of the CPAP system, thereby avoiding the dilution of the aerosolized surfactant and increasing the amount of aerosolized surfactant delivered to the patient's respiratory system, or providing a second gas flow in the respiratory circuit of lower volume than the first gas flow in the pressure-generating circuit. For either of these reasons, the rejection of claim

24 violates the third element of the *Graham* test, and must be withdrawn. Reconsideration and allowance of claim 24 is respectfully requested.

Regarding the rejection of claims 25-30, the claims depend from claim 24, which, as argued above, is believed to be allowable over the combination of art. Therefore, due to their dependence, claims 25-30 are also believed to be allowable. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claims 25-30 is respectfully requested.

In the event a telephone conversation would expedite the prosecution of this application, the Examiner may reach the undersigned at (408) 971-2573. For payment of any additional fees due in connection with the filing of this paper, the Commissioner is authorized to charge such fees to Deposit Account No. 19-0134 (Order No. 53428.US.NP).

Respectfully submitted,

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